

REMARKS

Claims 1, 3, 6-7, 9-18, and 21-40 are pending. Claims 1, 3, 6, 7, 9-18, 21-30, and 34-40 are allowed, and claims 17-18 and 31-33 are rejected.

Claim Rejections: 35 U.S.C. § 101

Claims 17-18 and 31-33 were rejected under 35 U.S.C. § 101 for not reciting subject matter eligible for patenting. The Examiner wrote (emphasis in Office Action):

These claims are directed to a process, which recites an abstract idea. This recitation falls within Section 101 judicial exceptions -Abstract Ideas.

The claims are directed to a judicial exception; as such, pursuant to the Interim Guidelines on Patent Eligible Subject Matter (MPEP 2106), the claims must have either physical transformation and/or a useful, concrete and tangible result. In making this determination, the focus is not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather on whether the **final result** achieved by the claimed invention is “useful, tangible, and concrete”. The claims fail to include transformation from one physical state to another in the final step. Although, the claims appear useful and concrete, there does not appear to be a tangible result claimed. Merely determining would not appear to be sufficient to constitute a tangible result, since the outcome of the determining step has not been used in a disclosed practical application nor made available in such a manner that its usefulness in a disclosed practical application can be realized. As such, the subject matter of the claims is not patent eligible.

Since the last step in claims 17 and 31 are not tangible, the entire claim is deemed to not comply with subject matter eligibility requirements.

Applicants ask the Examiner to reconsider and withdraw the rejection because the controlling case law makes clear that the determined result, or value indicative of a rate, recited in the rejected claims is itself a useful, concrete, and tangible result.¹

¹ Applicants note that the Examiner may not rely on the M.P.E.P. § 2106 Interim Guidelines to the extent that they are inconsistent with holdings of the U.S. Court of Appeals for the Federal Circuit.

The U.S. Court of Appeals for the Federal Circuit has held that “data, transformed by a machine through a series of mathematical calculations to produce a smooth waveform display on a rasterizer monitor, constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation), because it produced a ‘useful, concrete and tangible result’—the smooth waveform.” *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d 1368, 1373 (Fed. Cir. 1998) (quoting *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)).

Similarly, the Federal Circuit has held that “the transformation of electrocardiograph signals from a patient’s heartbeat by a machine through a series of mathematical calculations constituted a practical application of an abstract idea (a mathematical algorithm, formula, or calculation), because it corresponded to a useful, concrete or tangible thing—the condition of the patient’s heart.” *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d at 1373 (citing *Arrhythmia Research Technology Inc. v. Corazonix Corp.*, 958 F.2d 1053 (Fed. Cir. 1992)).

The Court maintained this view when deciding *State Street* itself, holding that “the transformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces “a useful, concrete and tangible result”—a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades.” *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d at 1373.

Here, the rejected claims require determining a result or a value indicative of a rate. That rate or result, just as in *State Street Bank*, *Arrhythmia*, and *Alappat*, is a useful, concrete, and tangible result, which, in the present claims, relates to the status of an assay performed for an analyte of interest. Accordingly, claims 14, 16-17, 21-23, and 30-31 recite subject matter eligible for patenting.

Respectfully submitted,

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